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REMARKS

Upon entry of the above amendments, only claims 1-4, 7-9, 17-20, 23, 24, 29, 30, and 34 will be pending. Applicants reserve the right to pursue subject matter that will no longer be pending, after the amendment above or which has not yet been pursued, in a related application. These amendments are introduced for the purpose of facilitating prosecution, to reduce the number of open issues, or to place the claims in better form for appeal, not for reasons related to patentability. Applicants submit that entry of the amendment above will not require a new search or raise new issues for consideration. Therefore, entry at this stage is proper, and Applicants thus respectfully request entry of the amend above amendment.

RESTRICTION REQUIREMENT

The Office action confirmed a four-way restriction requirement advanced telephonically on 20 February 2004 to Applicants' undersigned attorney, at which time Applicants' attorney provisionally elected the claims of Group I, namely independent claims 1 and 17 and the claims depending therefrom. Applicants hereby affirm that election, with claims 1-4, 7-9, 17-20, 23, 24, 29, 30, and 34 being readable on the elected species.

Applicants respectfully request reconsideration of the elected invention.

ART REJECTIONS

35 U.S.C. § 102(b)

Applicants respectfully traverse the rejection of claims 1-4, 7-9, 17-20, 23-26, and 29-34 under 35 U.S.C. § 102(b) as allegedly anticipated by, or, in the alternative, as supposedly being obvious under 35 U.S.C. § 103(a) over Leone, et al. (U.S. Pat. No. 5,505,700).

Regarding the alleged lack of novelty, a *prima facie* rejection of a claim for anticipation requires both that the cited reference provide an enabling disclosure and describe, either explicitly or inherently, all of the elements of the rejected claim(s). The '700 patent fails to anticipate any of the pending claims because, unlike the presently claimed invention, the apparatus disclosed in the '700 patent is not an electroporation apparatus; instead, the apparatus

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of the '700 patent is a catheter that provides for iontophoresis, which requires only a voltage drop between two spaced electrodes.

Applicants' invention, on the other hand, concerns electroporation devices wherein the first and second electrodes are configured in such a way as to allow the generation of an electric field of sufficient strength to electroporate cells in the vessel when a voltage is applied between the electrodes. The cited patent does not teach a device or system capable of electroporation as it is described in Applicants' invention. Electroporation, to the extent it is disclosed in the '700 patent, is directed to releasing components from cells by breaking those cells down (see column 7, lines 40 – 44), not for introducing components into cells. In contrast, as defined by Applicants, and as generally understood in the art, electroporation is a process for introducing molecules into cells, involving supplying a suitable voltage to a set of electrodes. In essence, the electric field generated during electroporation creates transient pores in cell membranes without permanently damaging the cells, allowing a desired therapeutic agent to be taken up and retained by the electroporated cells. *See, e.g.*, specification paragraphs 0022-25.

Additionally, the '700 patent does not disclose a catheter with a first electrode positioned adjacent to an infusion opening and a second electrode positioned such that the infusion opening is disposed between the first electrode and the second electrode, wherein the second electrode is spaced a distance that allows an electric field to be generated by a voltage applied between the first and second electrodes to transiently open pores in cells to allow molecules to enter the cells. Thus, the '700 patent not only fails to describe the devices invented and claimed by Applicants, it also fails to provide an enabling disclosure with respect to electroporation, as described by Applicants. Because the '700 patent does not teach each element of Applicants claimed devices, and because it fails to provide an enabling disclosure with regard to electroporation, Applicants respectfully submit that the '700 patent does not anticipate their invention as claimed, either before or after entry of the amendment above. For these reasons, Applicants ask that the instant rejection be withdrawn.

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35 U.S.C. § 103(a)

With respect to the supposed obviousness of the claims 29-34 in view of the '700 patent, Applicants also respectfully traverse. As an initial matter, they note that entry of the amendment above will obviate this rejection as to claims 31-33, in which subject matter Applicants' expressly reserve their rights. That said, to establish a *prima facie* case of obviousness, the burden is on the PTO to provide a convincing line of reasoning as to why the ordinarily skilled artisan would have modified the reference as suggested in the Office action, a reasonable expectation of success, and the presence, explicitly or by suggestion, of all of the elements of the rejected claim(s). *See MPEP 2142, et seq.*

Critically, the motivation must be found in the cited art, and can not be provided merely by conclusory statements set forth in an Office action. As discussed above, the '700 patent actually teaches away from the instant invention and in no way suggests, let alone teaches, any of the parameters necessary for applying a suitable voltage to a cell so as to electroporate it without damage for the purpose of introducing molecules, as specifically set forth in claims 29 - 34. The Office action mailed 8 September 2003 admits as much on page 4. Such parameters are not trivial additions. The appropriate electrode configuration (e.g., electrode spacing that allows generation of an electric field of strength to electroporate cells in the vessel) ensures that an electric field of a desired strength is indeed delivered, which is particularly important in the context of electroporation where small changes in electrode distance can have large effects on electric field strength and cell viability.

The '700 patent fails to acknowledge this concern, and, in fact, as stated above, teaches that "electroporation" causes the breakdown of the cell(s) in order to release intracellular components. This failure clearly demonstrates the '700 patent's deficiencies with regard to providing the requisite motivation, or enabling disclosure, with regard to Applicants' invention. Accordingly, the '700 patent does not render the claimed invention obvious. Thus, Applicants request that this rejection also be withdrawn.

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CONCLUSION

Applicants respectfully submit that, after entry of the amendment above, all pending claims will be in condition for allowance, and they earnestly solicit an early notice to such effect. That said, should any issues or questions remain, the Examiner is encouraged to telephone the undersigned at 858.350.9690 so that they may be promptly resolved.

Respectfully submitted,

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